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TECHNICAL CENTER 1609/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and
Scott Siegel

Application No.: 09/756,398 Group Art Unit: 1642
Filed: January 8, 2001 Examiner: Not assigned
Title: Anti-TNF Antibodies and Peptides of Human Tumor Necrosis Factor

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202	
on 3/29/02	Stacy McGarry
Date	Signature
STACY MCGARRY	

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
P.O. Box 2327
Arlington, VA 22202

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or

(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or

(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:

☐ a Statement under 37 CFR 1.97(e), as checked below, or

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:

☐ a Statement under 37 CFR 1.97(e), as checked below, and

☐ a \$180.00 fee under 37 CFR 1.17(p), or

(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):

Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.

(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

☒ Enclosed herewith is form PTO-1449:

☒ Copies of the cited references are enclosed.

☐ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]

☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.

☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:

☐ the explanation provided on the attached sheet.

☐ the explanation provided in the Specification.

☐ submission of the enclosed International Search Report.

☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.

☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

_____	U.S. Patent Application No. 09/766,535, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 18, 2001, Docket No.: 0975.1005-010
_____	U.S. Patent Application No. 09/897,724, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 2, 2001, Docket No.: 0975.1005-012
_____	U.S. Patent Application No. 09/927,703, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed August 10, 2001, Docket No.: 0975.1005-013
_____	U.S. Patent Application No. 10/010,229, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed December 7, 2001, Docket No.: 0975.1005-014
_____	U.S. Patent Application No. 10/043,450, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-015
_____	U.S. Patent Application No. 10/044,534, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-016
_____	U.S. Patent Application No. 10/043,432, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-017
_____	U.S. Patent Application No. 10/043,436, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-018

Examiner

Date

- [X] A copy of each above-cited application, including the current claims, is enclosed.
- [] A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated:

March 29, 2002

PTO-1449 REPRODUCED

ATTORNEY DOCKET NO.
0975.1005-006APPLICATION NO.
09/756,398INFORMATION DISCLOSURE CITATION
IN AN APPLICATIONAPPLICANT
Junming Le, et al.

APR 02 2002

March 29, 2002

FILING DATE
January 8, 2001GROUP
1642

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

EXAM- INER INI- TIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIA TE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATI ON YES NO
KAL	AO4	WO91/09967	11 JUL 91	PCT			
KAL	AP4	0486526B2	07 MAR 91	EPO			
KAL	AQ4	WO92/02190	10 JUN 92	PCT			
	AL5						
	AM5						
	AN5						

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

KAL	AV6	Whittle, Nigel, et al., "Construction and Expression of a CDR-Grafted Anti-TNF Antibody," <i>J. Cell Biochem</i> , Supl. 13A:96 (1989).					
KAL	AW6	Gorman, S.D. and Clark, M.R., "Humanisation of monoclonal antibodies for therapy," <i>Sem Immunol</i> , 2:457-466 (1990).					
KAL	AX6	Starnes, H. Fletcher, Jr., et al., "ANTI-IL-6 Monoclonal Antibodies Protect Against Lethal <i>Escherichia Coli</i> Infection and Lethal Tumor Necrosis Factor Challenge in Mice," <i>J Immunol</i> , 145:4185-4191 (1990).					

EXAMINER

Karen A. Gamelle

DATE CONSIDERED

1/10/03

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

NA	AY6	Duncombe, Andrew S. et al., "Tumor Necrosis Factor Mediates Autocrine Growth Inhibition in a Chronic Leukemia," <i>J Immunol</i> , 143:3828-3834 (1989).
	AZ6	Aderka, Dan et al., "IL-6 Inhibits Lipopolysaccharide-Induced tumor Necrosis Factor Production in Cultured Human Monocytes, U937 Cells, and in Mice," <i>J Immunol</i> , 143:3517-3523 (1989).
	AR7	Aderka, Dan, "Role of Tumor Necrosis Factor in the Pathogenesis of Intravascular Coagulopathy of Sepsis: Potential New Therapeutic Implications," <i>Isr J Med Sci</i> , 27:52-60 (1991).
	AS7	Lassalle, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," <i>Int Arch Allergy Appl Immunol</i> , 94:233-238 (1991).
	AT7	Fong, Yuman and Lowry, Stephen F., "Tumor Necrosis Factor in the Pathophysiology of Infection and Sepsis," <i>Clin Immunol Immunopathol</i> , 55:157-170 (1990).
	AU7	Eck, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor- α at 2.6 Å Resolution," <i>J Biol Chem</i> , 264:17595-17605 (1989).
	AV7	Gillies, Stephen D. et al., "High-level expression of chimeric antibodies using adapted cDNA variable region cassettes," <i>J Immunol Methods</i> , 125:191-202 (1989).
	AW7	Kameyama, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," <i>FEBS Lett</i> , 244:301-306 (1989).

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Karen A. Gamelle

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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

KAC	AX7	Hayashi, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," Recent Adv. Chemother, 820-821 (1985).
KAC	AY7	Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," J Immunol Methods, 96:57-62 (1987).
GAC	AZ7	Sunahara, N. et al., "Simple enzyme immunoassay methods for recombinant human tumor necrosis factor α and its antibodies using a bacterial cell wall carrier," J Immunol Methods, 109:203-214 (1988).

EXAMINER

DATE CONSIDERED

Karen A. Canale

1/10/03